UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/680,071	10/06/2003	Jason Artof	816020-100042-US	9944

34026 7590 10/06/2005

JONES DAY
555 SOUTH FLOWER STREET FIFTIETH FLOOR
LOS ANGELES, CA 90071

EXAMINER	
MILLER, CHERYL L	
ART UNIT	**PAPER NUMBER**
3738	

DATE MAILED: 10/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

PTO-90C (Rev. 10/03)

Office Action Summary	**Application No.** 10/680,071	**Applicant(s)** ARTOF ET AL.	
	Examiner Cheryl Miller	**Art Unit** 3738	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *21 July 2005*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3 and 5-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3 and 5-20* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

Applicant's arguments with respect to claims 1-3 and 5-20 have been considered but are moot in view of the new ground(s) of rejection.

The applicant has argued that Peredo (US 6,558,417) does not disclose a stent. However, the applicant has not claimed a stent. Applicant has claimed an anchoring structure adapted to support a valve. Peredo discloses a structure (12) which anchors the valve, providing support (the extra material provides further thickness and rigidity, thus support; Peredo discloses the anchor 12 to be "reinforcement" col.4, lines 31-35).

The applicant has argued that all of Garrison (US 6,425,916 B1), Spenser (US 6,730,118 B2), and Greenhalgh (US 6,494,909) may not be combined with Myers, since Myers discloses a valve for use without a stent. The examiner disagrees. Garrison, Spenser, and Greenhalgh each disclose an anchor and a valve. Myers teaches a specific shape of a valve, therefore relevant to Garrison, Spenser, and Greenhalgh. The fact that Myers does not disclose a stent on his valve is not relevant. This is because Myers is used as a teaching for the shape of a valve only, which applies to all valves, ones having a stent and ones absent of a stent (see rejections below for further explanation and motivation).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-3 and 5-20 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites, "expandable and collapsible anchoring structure adopted to support the replacement valve and being longitudinally displaced from the replacement outflow annulus". This statement is unclear, as the anchoring structure, as seen in the drawings, comprises an inflow rim, outflow rim, and support posts. The entire anchoring structure is ***not*** displaced from the valve annulus, only portions of it are. Some of the anchor is proximal the annulus, some is distal the annulus, and some of the anchor coincides longitudinally with the annulus, therefore, the anchoring structure as a whole, is not displaced from the valve annulus. This is a possible new matter issue, if not clarified/corrected in the next response. Claims 2-3 and 5-20 depend upon claim 1 and inherit all problems associated with the claim.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 and 20 are rejected under 35 U.S.C. 102(e) as being anticipated by Peredo (US 6,558,417 B2, cited previously). Peredo discloses a valve assembly (see fig.8) comprising a replacement valve (10) having a scalloped inflow annulus (see fig.3, 8; col.4, lines 1-10, 31-38), an outflow annulus, and a plurality of leaflets (11A-11C) in between the inflow and outflow annulus, an expandable and collapsible anchoring structure (12; made of a flexible material, thus *capable* of being collapsed/folded) adopted to support the valve (the extra material provides further thickness and rigidity, thus support; Peredo discloses the anchor 12 to be "reinforcement" col.4, lines 31-35) and being longitudinally displaced form the valve outflow annulus (top of anchor 12 is shown to be displaced above the outflow annulus, see fig.8) and dimensioned to extend longitudinally from an inflow attachment location to an outflow attachment location. Peredo discloses an anchoring structure (12) that is *capable* of collapsing to at least 50% the expanded diameter (due to the flexibility of the material).

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 1-3, 5-8, and 10-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Garrison et al. (US 6,425,916 B1, cited in IDS) in view of Myers et al. (US 2002/0052651 A1, cited previously). Referring to claim 1, Garrison discloses a valve assembly (see fig.31-38) comprising a replacement valve (6D) having an inflow annulus, an outflow annulus, and a plurality of leaflets in between the inflow and outflow annulus (fig.38), and an expandable and collapsible anchoring structure (8D) adapted to support the valve and being longitudinally displaced from the outflow annulus (the bottom of the anchoring structure is displaced below the outflow annulus and the top of the anchoring structure is displaced above the outflow annulus, see fig.38), the anchoring structure having an inflow rim (26d for example or 111 or 18) with an undulating configuration, and the anchoring structure dimensioned to extend longitudinally from an inflow attachment location to an outflow attachment location. Garrison however, discloses the inflow and outflow annulus to be straight rather than scalloped. Myers teaches in the same field of valve assemblies, the use of scalloped inflow and outflow annuluses on replacement valves like the one of Garrison (see figures 8, 9, 17, 28, and 29), as an improvement to straight annuluses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve [0088-0090]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Garrisons heart valve prosthesis, with Myers teaching of scalloping annuluses of valve prostheses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve.

Referring to claims 2-3, 5-8, and 10-20, Garrison discloses the valve (6D) to be positioned internally of the anchoring structure (8D) and to comprise three leaflets (fig.34, 38) and to be non self-expanding (may be expanded by way of balloon; see fig.3, 4). Garrison discloses the anchoring structure (8D) to comprise support posts (fig.36, 38; attachment 1) extending between and inflow and outflow rim, the posts having axially extending slots, the slots being generally triangular in shape (see attachment 1). Garrison discloses a plurality of rings that are undulating, parallel, and connected by a vertical element (support post). Garrison discloses an anchoring structure capable of collapsing to at least 50% of its expanded diameter (fig.36, 37).

Claims 1-3, 5-6, 18-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Greenhalgh (US 6,494,909 B2, cited in IDS) in view of Myers et al. (US 2002/0052651 A1, cited previously). Referring to claim 1, Greenhalgh discloses a valve assembly (see fig.9, 10) comprising a replacement valve (16) having an inflow annulus, an outflow annulus, and a plurality of leaflets (24, 26) in between the inflow and outflow annulus, and an expandable and collapsible anchoring structure (14+42+46) adapted to support the valve and being longitudinally displaced from the outflow annulus (see fig.6, 9, and 10, wherein the top of the anchor is below the outflow annulus), the anchoring structure having an inflow rim (14) with an undulating configuration and the anchoring structure dimensioned to extend longitudinally from an inflow attachment location to an outflow attachment location. Garrison however, discloses the inflow and outflow annulus to be straight rather than scalloped. Myers teaches in the same field of valve assemblies, the use of scalloped inflow and outflow annuluses on replacement valves like the one of Greenhalgh (see figures 8, 9, 17, 28, and 29), as an improvement to straight annuluses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve [0088-0090]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Greenhalgh's valve prosthesis, with Myers teaching of scalloping annuluses of valve prostheses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve.

Referring to claims 2-3, 5-6, and 18-20, Greenhalgh discloses the valve (16) to be positioned internally of the anchoring structure (may be woven into the anchor structure, therefore partially internal) and to comprise three leaflets (fig.8) and be non self-expanding (may be expanded by way of balloon; col.4, lines 25-30). Greenhalgh discloses the anchoring structure to comprise support posts (42) extending between and inflow and outflow rim. Greenhalgh discloses an inflow ring (14) having an undulating pattern. Greenhalgh discloses an anchoring structure (14+42+46) to be *capable* of collapsing to at least 50% of its expanded diameter (fig.3).

Claims 1-3 and 5-20 are rejected under 35 U.S.C. 103(a) as being unpatentable over Spenser et al. (US 6,730,118 B2, cited in IDS) in view of Myers et al. (US 2002/0052651 A1, cited previously). Referring to claim 1, Spenser discloses a valve assembly (see fig.23e, 26a, 27, 43a) comprising a replacement valve (430 for example) having an inflow annulus, an outflow annulus, and a plurality of leaflets in between the inflow and outflow annulus, and an expandable and collapsible anchoring structure (445 for example) adapted to support the valve and being longitudinally displaced from the outflow annulus (the anchor may extend above the outflow annulus as seen in fig.14 or below the outflow annulus as seen in fig.1, 11a, 20), the anchoring structure having an inflow rim (bottom rim; see figs.) with an undulating configuration and dimensioned to extend longitudinally from an inflow attachment location to an outflow attachment location. Spenser however, discloses the inflow and outflow annulus to be straight rather than scalloped. Myers teaches in the same field of valve assemblies, the use of scalloped inflow and outflow annuluses on replacement valves like the one of Spenser (see figures 8, 9, 17, 28, and 29), as an improvement to straight annuluses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve [0088-0090]. It would have been obvious to one having ordinary skill in the art at the time the invention was made to combine Spenser's valve prosthesis, with Myers teaching of scalloping annuluses of valve prostheses, in order to provide increased hemodynamic performance, minimized creasing, and an overall better fit within the native valve.

Referring to claims 2-3, 5-7, and 10-20, Spenser discloses the valve (430 for example) to be positioned internally of the anchoring structure (445 for example; see fig.26a) and to comprise three leaflets and may be non-self expanding (may expand by way of balloon, see figs; col.5). Spenser discloses the anchoring structure (445) to comprise support posts (440) extending between and inflow and outflow rim, the posts having axially extending slots (see in fig.24a, 25a, 28, 32a, and 42a, 42b). Spenser discloses a plurality of rings (portions of stent frame) that are undulating, parallel, and connected by a vertical element (support post; see fig.43a for example). Spenser discloses an anchoring structure capable of collapsing to at least 50% of its expanded diameter (fig.3, 4).

Referring to claim 8, Spenser discloses an anchoring structure having support posts with slots or apertures, however Spenser does not disclose the openings to be triangular. It would have been obvious to one having ordinary skill in the art at the time the invention was made to having triangular openings in the support posts, since the applicant has not disclosed triangular openings provides an advantage, is used for a particular purpose, or solves a stated problem. Further, because Spenser has shown the posts to have openings or slots, making the opening or slots triangular is merely an obvious change in shape. *In re Dailey*, 357 F.2d 669, 149 USPQ 47 (CCPA 1966).

As per claim 9, which depends upon claim 8, Spenser discloses a plurality of bores on either side of slots on the supports in order to provide attachment of commissural tabs (fig.42a, 42b).

Conclusion

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Cheryl Miller whose telephone number is (571) 272-4755. The examiner can normally be reached on Monday-Friday 7:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine McDermott can be reached on (571) 272-4755. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Cheryl Miller

BRUCE SNOW
PRIMARY EXAMINER